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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/346,923 07/02/99 DAWSON C 03543-0250-U

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EXAMINER

PESELEV, E

ART UNIT

PAPER NUMBER

1623

8

DATE MAILED:

04/14/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

Applicant(s)

Examiner

Group Art Unit

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 3/9/2000.
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-45 is/are pending in the application.
- ☐ Of the above claim(s) is/are withdrawn from consideration.
- ☐ Claim(s) is/are allowed.
- ☒ Claim(s) 1-45 is/are rejected.
- ☐ Claim(s) is/are objected to.
- ☐ Claim(s) are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 7
- ☒ Notice of References Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

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Claims 1-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bailey et al (Lancet, vol. 342, pages 453-456 (1993) in combination with Hauske et al (U.S. Patent No. 4,512,982) and WO 95/09601.

Bailey et al teach the use of azithromycin for the treatment of an eye infection but not disclose topical application of azithromycin to the eye. However, since Hauske et al (column 9, lines 24-35) disclose topical application of azithromycin derivative and WO 95/09601 discloses topical administration of azithromycin (see, for example, page 7, lines 29-32), a person having ordinary skill in the art at the time the instant invention was made would have been motivated to use azithromycin topically for the treatment of eye infections.

Claims 30-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 95/09601.

WO 95/09601 disclose a composition comprising azithromycin and a polymer see, for example, (page 5, lines 23-39). To vary the amount of the active ingredient would have been prima facie obvious to a person having ordinary skill in the art at the time the instant invention was made.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1 and 22-23 are rejected under 35 U.S.C. 102(b) as being anticipated by First Meeting of the WHO alliance for the Global elimination of Trachoma, Geneva, 30 June-1 July 1997 .

The First Meeting suggest the topical use of azithromycin to the treatment of an eye infection.

Claims 1-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over the First Meeting of the WHO alliance for the Global Elimination of Trachoma, Geneva, 30 June-1 July 1997 in combination with WO 95/09601.

The First Meeting suggests the use of azithromycin for the treatment of an eye infection bot does not disclose azithromycin in combination with polymers. However, since WO 95/09601 discloses azithromycin in combination with polymers, a person having ordinary skill in the art at the time the instant invention was made would have been motivated to combine azithromycin with polymers and to apply the resulting composition to an eye.

Claims 1-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is not clear what is encompassed by the term "prevent" (claim 1) i.e. it is not clear whether prevention is achieved for a period of days, months, years or whether permanent prevention is achieved.

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Applicant's arguments filed March 9, 2000 have been fully considered but they are not persuasive insofar as the above rejections relate to the claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peslev whose telephone number is (703) 308-4616. The examiner can normally be reached on weekdays from 9.30 a.m. to 6.00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Geist, can be reached on (703) 308-1701. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Elli Peslev
**ELLI PESELEV
PRIMARY EXAMINER
GROUP 1200**